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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MALLARI, PATRICIA C	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/677,694	NAJAFI ET AL.	
	Examiner	Art Unit	
	Patricia C. Mallari	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44,46-63 and 65-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44,46-63 and 65-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This is a final Office action. Any new grounds of rejection were necessitated by the applicant's amendments to the claims.

The drawings were received on 2/2/06. These drawings are accepted.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-44, 46-63, and 65-72 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 1 recites the limitation " at least one sensing device implanted in a cavity of the patient's cardiovascular system, " "at least one sensing device being implanted", " anchoring mechanism passes through a septum of the heart," " a larger portion of said implantable sensing device is located in the right side of the heart," and "a smaller portion of said implantable sensing device is located in the left side of the heart". Claim 2 recites, "at least one sensing device implanted in a cavity of the patient's cardiovascular system". Claim 11 recites "at least one sensing device is implanted", wherein "implanted" is taken to mean "implanted in a human body". Claim 13 recites, "at least one sensing device is implanted" wherein "implanted is taken to mean, "implanted in a human body". Claim 25 recites the limitation, "at least one sensing device is implanted at a location chosen from the group consisting of" wherein the following locations are within a human body. Claim 26 recites "the at least one sensing device is implanted at a location chosen from the

group consisting of", wherein the following locations are locations within a human body. Claim 31 recites "at least one sensing device implanted in a cavity of the patient's cardiovascular system". Claim 42 recites, "anchoring means comprises means opening on at least one side of the septal wall, clamping said implantable device to the septal wall". Claim 43 recites, "said anchoring mechanism passes through the atrial septum of the heart". Claim 47 recites, "a tine that catches on a trabeculated area of the heart". Claim 50 recites, "a portion passing through a septum wall of the heart and means opening on at least one side of the septal wall and clamping said implantable device to the septal wall". Claim 51 recites, "a portion passing through the atrial septum of the heart". Claim 52 recites, "two umbrella-shaped anchors disposed on opposite sides of the atrial septum". Claim 53 recites, "a larger portion located in the right side of the heart and a smaller portion located in the left side of the heart". Claim 55 recites "a tine that catches on a trabeculated area of the heart". In every single case the claim language positively recites the human body or some portion thereof. The human body or any portion thereof is non-statutory subject matter and cannot positively be claimed. As an example of overcoming this rejection, the limitation on lines 4-5 of claim 1 should be replaced with "at leas tone sensing device adapted to be implanted in a cavity of the patient's cardiovascular system".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 6, 9, 11, 19, 23, 25, 27, 29, 37, 38, 41-44, 46-48, 57, 69 and 70 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,636,769 to Govari et al. Govari teaches a system for monitoring one or more physiological parameters for diagnosis or treatment of congestive heart failure (CHF) within a patient. The system comprises at least one implantable sensing device adapted to be implanted in a cavity of the patient's cardiovascular system. The sensing device comprises an anchoring mechanism and has at least one inductor coil 68 and at least one sensor. The sensing device of Govari may be implanted in the body such that a portion of the anchoring mechanism passes through the septum of the heart (figs. 1, 3-5, 11; col. 5, lines 39-47; col. 6, lines 22-col. 7, line 21; col. 10, lines 1-60 of Govari). A non-implantable readout device 140, has at least one inductor coil 162 having telemetric means for electromagnetic telecommunication and/or electromagnetic wireless powering (fig. 8; col. 7, line 58-col. 8, line 5; col. 8, lines 33-65 of Govari).

As to the limitation "a larger portion of said implantable sensing device is located on the right side of the heart and a smaller portion of said implantable sensing device is located in the left side of the heart and includes the at least one sensor" Fig. 11 of Govari shows the larger portion of the sensing device being located on *a* right side of the heart. While Govari discloses 410 to be the left atrium and 415 the right atrium in

figure 10, the applicants should note that the orientation of the device during implantation is merely "intended use" language which cannot be relied upon to define over the prior art since Govari teaches all of the claim limitations and their recited relationships. The device of Govari is certainly capable of being implanted so that the larger portion of the device is placed in either the left or right sides of the heart.

Regarding claims 5 and 6, the sensing device 50 includes a battery, wherein the charge capacitor 114 acts as a battery (col. 7, line 48-col. 8, line 5 of Govari). With further regard to claim 6, the battery or charge capacitor 114 is rechargeable using wireless means (col. 7, line 48-col. 8, line 5 of Govari).

Regarding claims 9, 11, and 23, the sensor 50 may sense pressure (col. 6, lines 5-14; col. 9, lines 17-40; col. 10, lines 50-60 of Govari). With further regard to claim 11, the sensor 50 may measure any left ventricular, left atrial, right ventricular, or right atrial pressure (col. 10, lines 50-60 of Govari).

Regarding claim 19, a passive scheme is used (col. 8, lines 38-46 of Govari).

Regarding claim 25, the device may be located at the atrial septum, left or right atrium, or left or right ventricle of the heart (figs. 10 & 11; col. 10,lines 50-67 of Govari).

Regarding claim 27 the applicants should note that the intended use of the invention cannot be relied upon to define over the prior art, since Govari teaches all of the claimed structural elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. The system of Govari may certainly be used to determine drug treatment for a patient or for disease management, for example.

Regarding claim 29, the readout device 140 is capable of performing remote monitoring of congestive heart failure patients or of portable or ambulatory monitoring or diagnosis (col. 10, lines 2-67 of Govari).

Regarding claims 37 and 38, the implantable device 50 is capable of being implanted using a minimally invasive outpatient technique or catheter delivery method (cols. 11 and 12 of Govari).

Regarding claims 41-44 and 46-48, the implantable device 50 uses an anchoring mechanism including a septal occluding device, a screw, or a tine (figs. 1, 3, 4, and 11; col. 6, lines 39-65; col. 10, lines 59-60 of Govari). With further regard to claims 42-45 and 50-53, the anchor passes through a septum wall and opens on one side of the wall, clamping the device to the wall (fig. 11; col. 10, lines 59-60 of Govari). With further regard to claims 44 and 52, the anchoring mechanism utilizes two umbrella shaped anchors 64, one on each side, which anchor the sensing device 50 (fig. 11 of Govari). With further regard to claims 45 and 53, a larger portion of the implantable device 50 is located on the right side of the heart while a smaller portion is located in the left side of the heart (fig. 11 of Govari). With further regard to claims 46 and 54, the anchoring mechanism is a helical screw (fig. 3 of Govari). With further regard to claims 48 and 56, the anchoring mechanism is made from nitinol (col. 6, lines 43-45 of Govari).

Regarding claim 57, the implantable sensing device 50 is augmented with a radiation emitting source 100 (fig. 6A & B; col. 7, lines 15-17 of Govari).

Regarding claims 69 and 70, at least a portion of the implantable sensing device 50 is coated with one or more layers of thin coating 52 (fig. 5; col. 5, lines 49-51 of Govari), wherein the coating comprises titanium and polysilicon.

Claims 1, 9, 11, 12, 23, 25, 27, 37, 38, 41, 43, 46, 47, 57, and 59 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,409,674 to Brockway et al. Brockway describes a system for monitoring at least one physiological parameter, the system comprising at least one implantable sensing device 105 and at least one non-implantable readout device 140 (figs. 1, 2, 4, and 5 of Brockway). The implantable device 105 comprises an anchoring mechanism, at least one inductor coil and at least one sensor 305 (col. 8, lines 13-15; col. 10, lines 15-25 of Brockway). The readout device 140 comprises at least one inductor coil allowing electromagnetic telecommunication and powering (col. 7, lines 42-55; col. 10, lines 15-25 of Brockway).

As to the language "for monitoring . . . for diagnosis of congestive heart failure" on lines 1-2 of claim 1 and "for monitoring . . . for treatment of congestive heart failure" on lines 1-2 of claim 2, the applicants should note that this is merely "intended use" language which cannot be relied upon to define over the prior art, since Brockway teaches all of the claimed structural elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. The system of Brockway is fully capable of being used for either diagnosis or treatment of congestive heart failure in a patient (col. 1, lines 38-60 of Brockway). The orientation of the sensing device upon implantation

("sensing device being implanted so that a portion of said anchoring mechanism passes through a septum of the heart and . . . a larger portion of the implantable sensing device is located in the right side of the heart and a smaller portion of the implantable sensing device if located in the left side of the heart. . .") is similarly intended use language which cannot be relied upon to define over the prior art since Brockway teaches all of the claimed limitations and their recited relationships. The device of Brockway is certainly *capable* of being implanted in such a way as described in claim 1.

Regarding claims 9, 11, 12, 23 and 25 the system is for monitoring pressure, wherein the pressure transducer 305 may be placed in any one of the chambers of the heart and therefore may measure any right or left atrial or ventricular pressure (col. 7, lines 14-37 of Brockway). With further regard to claims 12 and 14, the system calculates the change of pressure over time (dp/dt) (col. 1, lines 30-55; col. 9, lines 33-41 of Brockway).

Regarding claim 19, a passive scheme is used (col. 10, lines 15-25 of Brockway).

Regarding claim 27 the applicants should note that the intended use of the invention cannot be relied upon to define over the prior art, since Brockway teaches all of the claimed structural elements and their recited relationships. See Ex parte Masham 2 USPQ 2nd 1647. The system of Brockway may certainly be used for disease management or pacing adjustments, for example (col. 11, lines 35-62; col. 14, lines 37-40 of Brockway).

Regarding claim 29, the readout device 140 is capable of closed-loop pacemaker parameter tuning to treat CHF or CHF related conditions, portable or ambulatory

monitoring, data storage, and communication with other medical devices, including pacemakers, for example (figs. 1, 2, 4, and 5; col. 11, lines 14-62; col. 14, lines 30-40 of Brockway).

Regarding claims 37 and 38, the implantable device 105 is implanted using a minimally invasive outpatient technique or catheter delivery method (col. 1, line 65-col. 1, line27; col. 12, line 56-col. 13, line 17 of Brockway).

Regarding claims 41, 43, 46, and 47 the implantable sensing device 105 uses an anchoring mechanism including a screw 312A, tine 312B, 312D, or stent 312C (figs. 3A-D; col. 8, lines 26-52 of Brockway). With further regard to claims 43, 45, 51, and 53, the anchor 312A, 312B is capable of passing through an atrial septum. With further regard to claim 46, the anchoring mechanism is a helical screw 312A (fig. 3A of Brockway). With further regard to claim 47, the anchoring mechanism is a tine 312D that expands (figs. 3D and 7; col. 8, lines 45-52; col. 13, lines 43-47 of Brockway), wherein the expandable tine 312D is capable of catching on a trabecular area of the heart.

Regarding claim 57, the implantable sensing device 105 is augmented with a pacing stimulator or defibrillator 400, for example (figs. 4 & 5; col. 11, lines 14-62 of Brockway).

Regarding claim 59, the system is part of a closed-loop pacing/ICD tuning mechanism where the data from the sensor 305 is sent to a patient pacemaker for tailoring of pacing/ICD function (figs. 4 & 5; col. 11, lines 14-62 of Brockway).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Govari, as applied to claims 1, 5, 6, 9, 11, 19, 23, 25, 27, 29, 37, 38, 41-44, 46-48, 57, 69 and 70 above, and further in view of US Patent No. 5,207,103 to Wise et al. Govari teaches the sensor as being a deflecting membrane in conjunction with an LED. However, Wise teaches using a capacitive pressure sensor in an implantable medical device (abstract; col. 5, line 10-col. 6, line 3 of Wise). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the capacitive sensor of Wise in the device of Govari, as it would be the mere substitution of one known means for measuring pressure for another.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Govari, as applied to claims 1, 5, 6, 9, 11, 19, 23, 25, 27, 29, 37, 38, 41-44, 46-48, 57, 69 and 70 above, and further in view of US Patent No. 6,287,253 to Ortega. Govari uses a passive scheme rather than a resonant scheme to couple the sensing device to the readout device. However, Ortega teaches a medical sensor using a resonant scheme to couple a sensing device with a readout device (fig. 4; col. 8, line 19-37 of Ortega). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the resonant scheme of Ortega in place of the passive scheme of

Govari as it would merely be the substitution of one known communication scheme for another.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Govari, as applied to claims 1, 5, 6, 9, 11, 19, 23, 25, 27, 29, 37, 38, 41-44, 46-48, 57, 69 and 70 above, and further in view of US Patent No. 6,231,516 to Keilman et al. Govari teaches using a passive scheme to couple the sensing device and readout device. However, Keilman teaches using either a passive or an active scheme to couple a sensing device and a readout device (col. 8, lines 20-39; col. 13, lines 54-65 of Keilman). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use an active scheme in place of the passive scheme of Govari, since Keilman teaches both schemes to be functionally equivalent.

Response to Arguments

Applicant's arguments filed 2/2/06 have been fully considered but they are not persuasive.

On p. 42 of the response filed 2/2/06, the applicants state, with respect to the rejection under 35 U.S.C. 101, that they believe that the claims do not positively claim any portion of the human body. However, the examiner disagrees. The positive recitation of the human body or parts thereof is listed in the rejection under 35 U.S.C. 101 above.

With respect to the rejection of claim 1 as being anticipated by Govari, the applicants argue that Govari disclose the larger portion of the device being located in

the left side of the heart and the smaller portion in the right. However, the orientation of the device *during implantation* amounts to nothing more than language describing an intended use of the claimed invention. See the rejections above as to how the device of Govari may be used in such a manner.

With respect to the rejection of claim 1 as being anticipated by Brockway, the applicants contend that they "can find no teaching in Brockway" to the effect of a larger portion of an implantable device located on the right side of the heart and a smaller portion located in the left side of the heart or of a screw, etc., being inserted through a wall of the heart. Again, the applicant's are relying upon "intended use" language to define over the prior art. Since the limitations are merely intended use, the prior art must merely be *capable* of performing the recited use. The device of Brockway is certainly *capable* of being used such that a larger portion is located on the right side of a heart and a smaller portion is located in the left side or such that the anchoring mechanism is inserted *through* the wall of the heart, as described above.

Allowable Subject Matter

Claims 2, 4, 7, 8, 10, 13-16, 18, 20, 22, 24, 26, 28, 30, 31-36, 39, 40, 49-56, 58, 60-63, 65-68, 71, and 72 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 101, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The allowability of claims 31, 32, 60-63, and 65-58 was addressed in a previous Office action filed 11/2/05. Claims 2, 4, 7, 8, 10, 13, 14, 16, 18, 20, 22, 24, 26, 28, 30,

32, 35, 36, 39, 40, 49-56, 58, 65-68, 71, and 72 incorporate the allowable subject matter of claims 60-63.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claim 15, the prior art of record fails to teach or fairly suggest a system wherein the sensing device sends data directly to a drug delivery device to tailor drug treatment of the patient, in combination with all of the other limitations of the claim.

Regarding claims 33 and 34, the prior art of record fails to teach or fairly suggest a system wherein the non-implantable readout device includes a barometric pressure sensor, in combination with all of the other limitations.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia C. Mallari whose telephone number is (571) 272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Mallari
Patent Examiner
Art Unit 3736

ROBERT L. NASSER